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APR 24 1997

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In re Riker Laboratories, Inc. : NOTICE OF FINAL
Request for Patent Term Extension : DETERMINATION
U.S. Patent No. 5,439,670 :

An application for extension of the patent term of U.S. Patent No. 5,439,670 under 35 U.S.C. § 156 was filed in the United States Patent and Trademark Office on October 11, 1996. The application was filed by Riker Laboratories, Inc., the patent owner of record. Extension is sought based upon the premarket review under § 505(b) of the Federal Food, Drug, and Cosmetic Act (FFDCA) of a product identified as PROVENTIL® HFA having the active ingredient albuterol sulfate. PROVENTIL® HFA was given permission for commercial marketing and use by the Food and Drug Administration (FDA) on August 15, 1996.

Since the active ingredient, albuterol sulfate, had been previously approved prior to the approval of PROVENTIL® HFA, the patent has been determined to be ineligible for patent term extension based upon the regulatory review period of PROVENTIL® HFA.

The FDA official records indicate that albuterol sulfate was previously approved for commercial marketing or use prior to the approval of PROVENTIL® HFA. In a letter dated January 13, 1997, FDA stated:

> However, our records indicate that it **does not** represent the first permitted commercial marketing or use of the product. For example, Ventolin, Volmax, Combivent, and Albuterol Sulfate have been previously approved . . . and contain the same active ingredient in PROVENTIL® HFA, albuterol sulfate.

Under 35 U.S.C. § 156(a) a term of a patent which claims a product shall be extended if, inter alia, the product has been subject to a regulatory review period before its commercial

marketing or use. In addition, under § 156(a)(5)(A):

> the permission for the commercial marketing or use of the product . . . is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred; (Emphasis added)

Thus, the determination of eligibility of U.S. Patent No. 5439,670 turns on the provisions in § 156(a)(5)(A) that the permission for the commercial marketing or use is the first permitted commercial marketing or use of the product. The term "product" is defined in 35 U.S.C. § 156(f) as follows:

> (f) For purposes of this section:
> (1) The term "product" means:
> (A) A drug product . . .
> (2) The term "drug product" means the active ingredient of -
> (A) A new drug, antibiotic drug, or human biological product . . . including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient. (Emphasis added.)

By the explicit terms of section 156(f)(2), the term "product" as it relates to a human drug product means the active ingredient of the new drug product. The active ingredient in the approved product, PROVENTIL® HFA, is albuterol sulfate. As noted in the above FDA letter, the active ingredient albuterol sulfate had been approved for commercial marketing and use prior to the approval of the applicant's product. Applying the definition of "product" provided in section 156(f) to the extension requirement of § 156(a)(5)(A), applicant's product PROVENTIL® HFA does not qualify as the first permitted marketing or use of the active ingredient. Since the approval of PROVENTIL® HFA (albuterol sulfate) was not the first permitted marketing or use of the active ingredient thereof, albuterol sulfate, the patent is not eligible for patent term extension based upon the regulatory review of PROVENTIL® HFA. See In re Fisons Pharmaceuticals Limited, 231 USPQ 305 (Comm'r Pats. 1986); aff'd Fisons plc v. Quigg, 8 USPQ2d 1491 (DDC 1988); aff'd. Fisons plc. v. Quigg, 10 USPQ2d 1869 (Fed. Cir. 1988); Glaxo Operations UK Ltd. v. Quigg, 13 USPQ 1628 (Fed. Cir. 1990).

In view of all the above, the term of U.S. Patent No. 5,202,128 is not eligible for extension under 35 U.S.C. § 156 based upon the approval of the product PROVENTIL® HFA and the application for patent term extension, filed October 11, 1996, is dismissed. A single request for reconsideration of this FINAL DETERMINATION OF INELIGIBILITY may be made if filed by the applicant within TWO MONTHS of the mailing date of this letter. The period for response may be extended pursuant to 37 C.F.R. 1.136. See 37 C.F.R. 1.750. A failure to respond to this letter will result in the application papers being placed into the patent file with no further action taken on the application for patent term extension.

Any response should be addressed as follows:

By mail: Assistant Commissioner for Patents
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By FAX: (703) 308-6916
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Telephone inquiries should be directed to Karin Tyson at (703) 305-9285.

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cc: RONALD L. WILSON, DIRECTOR
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RE: PROVENTIL® HFA
FDA Docket No: 96E-0466